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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/775,648	02/05/2001	Toshiaki Takezawa	202785US0X	3290
22850	7590	12/16/2003		
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER MARVICH, MARIA	
			ART UNIT 1636	PAPER NUMBER
DATE MAILED: 12/16/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

09/775,648

Applicant(s)

TAKEZAWA ET AL.

Examiner

Maria B Marvich, PhD

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-9, 11-23 and 27-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9, 23, 27 and 29-31 is/are allowed.
- 6) ☒ Claim(s) 4, 5, 7, 8, 11, 13, 17-22, 28 and 32-36 is/are rejected.
- 7) ☒ Claim(s) 6, 12 and 14-16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

This office action is in response to a Request for Continued Examination and an amendment filed 12/1/03. Claims 1-3, 10, 24-26 have been cancelled. Claims 32-36 have been added. Claims 4, 6-9, 11, 17-18, 20-23 and 29-30 have been amended. Claims 4-9, 11-23, 27-36 are pending in this application. Receipt of a Substitute specification is acknowledged. The Substitute Specification has been entered.

Claim Objections

Claims 6 and 20 are objected to because of the following informalities: Claim 6 is grammatically incorrect in reciting that the cell to be incorporated in the cell incorporated type three-dimensionally reconstructed tissue are pretreated with mitomycin C.”, Claim 20 has an incorrectly placed comma that separates the preamble into two sections.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4-5, 8, 18-21 and 32-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4-5, 18-20, 32-33 and 34-35 are vague and indefinite in that the metes and bounds of the term “derived from” are unclear. It is unclear the nature and number of steps required to

obtained a “derivative” of cells or biological material. The term implies a number of different steps that may or may not result in a change in the functional characteristics of the cells or biological material from the source that it is “derived from”. It would be remedial to amend the claim language to use the term “obtained from”, which implies a more direct method of acquiring the cells or biological material.

Claim 8 recites the limitation "the mesh network" in claim 6. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 7, 11, 13, 17-20, 22, 28, 32-33 and 36 are rejected under 35 U.S.C. 102(e) as being anticipated by Spaulding et al., US patent 6,001,643.

Spaulding et al teach use of a hydrodynamic cell culture environment comprised of a tissue culture chamber for three-dimensional tissue growth (abstract and column 9, line 44-57).). As a general method, tissue is introduced into a roller bottle that is constructed of material suitable for cell and tissue culture i.e. polystyrene, nylon and the like (column 7, line 20-30). Cells are suspended in media in the chamber and as the cells aggregate, they form an autologous

extracellular matrix upon which cells adhere, differentiate and become 3-dimensional tissue (column 14, line 61–column 15, line 1). Specifically for use in developing embryos, Spaulding et al teach co-culturing of a fertilized ovum of an animal with endometrial tissue in the chamber. Therefore, the carrier of Spaulding et al comprises a scaffold (endometrial tissue) for the cellular growth of a fertilized egg once it is implanted. Spaulding teaches that the endometrial tissue (which is comprised of epithelial cells and stromal cells) is co-cultured with the fertilized egg such that endometrial implantation constructs are formed that support endometrial maturation until it is transplanted into a recipient uterus (example 8, column 20, line 29-56).

Response to Arguments

Applicants traverse the rejection under 35 U.S.C. 112, second paragraph in the amendment filed 12/1/03. Applicants argue that the indefiniteness is alleviated by the amendments to the claims.

The arguments filed 12/1/03 have been considered but are not persuasive. Pending claims 4-5, 18-20, 32-33 and 34-35 have not been amended to overcome the rejection. The claims recite that the carrier is comprised of cells that are derived from an animal or an endometrium. The word derived suggests a number of steps, which are not defined in the specification for which the prior art has no defined meaning. The nature and number of steps to follow to derive the cells of the cell-incorporated type three-dimensionally reconstructed tissue from an animal or endometrium are undefined. Therefore, the claims are indefinite.

Conclusion

Claims 4-5, 7-8, 11, 13, 17-22, 28 and 32-36 are rejected.

Claims 9, 23, 27, 29-31 are allowed.

Claim 6 is objected to.

Claims 12, 14-16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (703) 605-1207. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3553.

Maria B Marvich, PhD
Examiner

Gerry Leffers
Art Unit 1636
GERRY LEFFERS
PRIMARY EXAMINER

December 15, 2003